

In this edition...

The concept of a "Commercialise in Australia First" strategy for biotech companies is beginning to take hold, with Mesoblast and Pharmaxis looking to launch products in Australia prior to entry into EU or US markets. One argument for this strategy is that an Australian launch is a means to iron out the bugs in the market strategy. And speaking of bugs, we profile Ondek, a private company founded by Nobel Prize winner Dr Barry Marshall, that is developing a drug delivery platform based on the bacteria *H. pylori*. The technology could revolutionise vaccination. We also update readers on progress at Starpharma and note a fundraising underway at Sunshine Heart.

The Editors

Companies Covered: MSB, SHC, SPL, Ondek

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.0%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.3%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.3%
Year 9 (May '09 - Current)	22.0%
Cumulative Gain	137%
Av Annual Gain (8 yrs)	14.7%

Bioshares is published by Blake Industry & Market Analysis Pty Ltd.

Blake Industry & Market Analysis Pty Ltd
ACN 085 334 292
PO Box 193
Richmond Vic 3121
AFS Licence
No. 258032

Enquiries for *Bioshares*
Ph: (03) 9326 5382
Fax: (03) 9329 3350
Email: info@bioshares.com.au

David Blake
Ph: (03) 9326 5382
Email: blake@bioshares.com.au

Mark Pachacz
Ph: (03) 9671 3222
Email: pachacz@bioshares.com.au

Individual Subscriptions (48 issues/year)
\$320 (Inc.GST)
Edition Number 322 (31 July 2009)
ISSN 1443-850X

Copyright 2009 Blake Industry and Market Analysis Pty Ltd. ALL RIGHTS RESERVED.
Secondary electronic transmission, photocopying, reproduction or quotation is strictly prohibited without written consent of the publisher.

Bioshares

31 July 2009
Edition 322

Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies.

Extract from Bioshares –

Biotech Divide Continues

The divide between those biotechs that are looking likely to succeed and those that don't to continues to broaden. What the Tier-1 biotechs are doing right, or the smaller biotechs that look to have their business plans on track with commercial and financial viability, is becoming clearer each month. This divide is being accentuated by the difficult market conditions imposed by the global financial crisis which now looks to be easing.

Over the next 12-18 months we will see several of the leading biotechs in the sector bring their products to market. **Alchemia's** generic fondaparinux should be released in the US in the first half of 2010, with profit share income we estimate at over \$30 million a year with rapid market penetration. **Universal Biosensors** will start manufacturing its glucose strips for **Life Scan** towards the end of this year, bringing in around \$25 million of revenue in the first 12 months. **CathRx** has released its forecast for the next two years with sales expected to reach \$5.4 million in this financial year and \$21.3 million in FY2011.

Pharmaxis, Chemgenex Pharmaceuticals, Clinuvel Pharmaceuticals, QRxPharma, Acrux (with its male testosterone product Axiron), **Halgcygen Pharmaceuticals, Biota Holdings** (with its LANI product in Japan, co-developed with **Daiichi Sankyo**) and now Mesoblast are on track to see their drug products and therapies reach the market over the next 12-24 months. There are 23 profitable companies in the sector (see Bioshares 306) with a number of other companies building sales with recently released products. These include **Acrux** (Evamist), **Labtech Systems, Atcor Medical, Nanosonics, Impedimed** and **Tyrian Diagnostics**, with sales traction progress worth following.

Starpharma – Getting it Right

Starpharma (SPL: \$0.37) is one company which seems to getting it right, with the main focus on the microbicide application for condom coating. It's partner **SSL International**, which continues to build its dominance in the global condom market, is expected to start selling microbicide coated condoms using a microbicide developed by Starpharma.

This will be the only microbicide on the market when the product is released in the second half of 2010. Product uptake should be rapid after the initial introduction, with SSL now commanding a 40% share of the global condom market. (SSL recently purchased a major share in two market leading condom makers in Eastern Europe and Russia.) Starpharma initially expected that its deal with SSL will bring in over \$100 million in revenue over the life of the deal. However, it looks likely that the product application of the microbicides for the condom market may be broader than earlier anticipated, and by our estimates significantly larger.

In May Starpharma raised \$7.1 million, confirming the heightened interest in this company. The proximity to market for Starpharma has seen not only the more traditional biotech investors taking an interest in Starpharma, but more general fund interest according to the company's CEO Dr Jackie Fairley.

Cont'd over

At the end of June, the company had \$11.6 million in cash and had reduced its cash burn considerably, from \$6.1 million in FY2008 to \$2.9 million in the last year. The difficult market conditions has seen a deliberate reduction on expenditure, with more of a focus on late stage product applications, such as the condom coating product, and funded R&D collaborations such as those with Stiefel Laboratories (now part of GlaxoSmithKline) and Elanco (Eli Lilly).

In December, Starpharma entered into a collaboration with Stiefel to apply its chemistry platform to improve the properties of dermatology treatments. And in May it teamed up with Elanco to apply the same technology to develop improved animal health products. Incorporating the company's dendrimer chemistry scaffold has the potential to increase the half life of drugs and the way the drugs are distributed and absorbed in the body.

The DNT subsidiary business in the US has also for the first time become cash flow positive, currently generating US\$500,000 positive cash flow on an annualised basis.

Regulatory Approval

It is not expected that efficacy trials will be required by regulators to have the microbicide condom product approved for sale, although there is continuing dialogue with regulators, and small safety studies will be a requirement, along with stability testing and durability testing. The raw material manufacture is contracted out to third parties. Commercialisation of the standalone Vivagel microbicide product is continuing, however the focus has been on lead product and revenue generating aspects of the business.

Summary

As we approach the end of this decade, we expect to see companies such as Starpharma generate a very real return from the investments made in product development over this period. Highly profitable businesses are emerging in the sector such as **Biota Holdings**, **Sirtex Medical**, **Arana Therapeutics** (majority owned by **Cephalon**) and **Cellestis**. The next two years should see this list expand significantly.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

How Bioshares Rates Stocks

For the purpose of valuation, *Bioshares* divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, *Bioshares* grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks.

Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

- Buy** CMP is 20% < Fair Value
 - Accumulate** CMP is 10% < Fair Value
 - Hold** Value = CMP
 - Lighten** CMP is 10% > Fair Value
 - Sell** CMP is 20% > Fair Value
- (CMP–Current Market Price)

Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

Speculative Buy – Class A

These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

Speculative Buy – Class B

These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

Speculative Buy – Class C

These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C

Sell

Corporate Subscribers: Phylogica, Pharmaxis, Cytopia, Arana Therapeutics, Starpharma Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical, CathRx

Disclaimer:

Information contained in this newsletter is not a complete analysis of every material fact respecting any company, industry or security. The opinions and estimates herein expressed represent the current judgement of the publisher and are subject to change. Blake Industry and Market Analysis Pty Ltd (BIMA) and any of their associates, officers or staff may have interests in securities referred to herein (Corporations Law s.849). Details contained herein have been prepared for general circulation and do not have regard to any person's or company's investment objectives, financial situation and particular needs. Accordingly, no recipients should rely on any recommendation (whether express or implied) contained in this document without consulting their investment adviser (Corporations Law s.851). The persons involved in or responsible for the preparation and publication of this report believe the information herein is accurate but no warranty of accuracy is given and persons seeking to rely on information provided herein should make their own independent enquiries. Details contained herein have been issued on the basis they are only for the particular person or company to whom they have been provided by Blake Industry and Market Analysis Pty Ltd. The Directors and/or associates declare interests in the following ASX Healthcare and Biotechnology sector securities: AAH, ACL, ACR, ADO, BTA, CGS, CSL, CST, CXD, CYT, CUV, CXS, HXL, IDT, IMU, MBP, PAB, PBB, PLI, PXS, SHC, SPL, TIS,UBI. These interests can change at any time and are not additional recommendations. Holdings in stocks valued at less than \$100 are not disclosed.

Subscription Rates (inc. GST)

48 issues per year (electronic distribution): **\$320**

For multiple email distributions within \$550 2-3 email addresses
 the same business cost centre, our \$750 4-5 email addresses
 pricing structure is as follows: \$950 6-10 email addresses

To subscribe, post/fax this subscription form to:

Bioshares
PO Box 193 Richmond VIC 3121
Fax: +61 3 9671 3633

I enclose a cheque for \$ _____ made payable to **Blake Industry & Market Analysis Pty Ltd**, or

Please charge my credit card \$ _____ MasterCard Visa

Card Number

Signature _____ Expiry date _____

Subscriber details

Name _____

Organisation _____

Ph () _____

Emails _____
